Miller, Diane M. (CDC/NIOSH/EID)

From: Cynthia Reilly [CReilly@ashp.org]
Sent: Thursday, September 20, 2007 9:16 AM
To: NIOSH Docket Office (CDC)
Cc: Justine Coffey; Brian Meyer; Kasey Thompson
Subject: 105 - HazDrug Update Comments
Attachments: Hazardous Drugs Comments Final.pdf

NIOSH Docket Office Staff:

On behalf of the American Society of Health-System Pharmacists, I am submitting comments pertaining to the proposed update to the list of hazardous drugs (Appendix A) for the *NIOSH Alert on Hazardous Drugs*. The Society is pleased to have an opportunity to provide feedback on this important process. Please contact me with any questions you may have on our submission.

Regards,
Cindy

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September 20, 2007

NIOSH Mailstop: C-34
Robert A. Taft Lab.
4676 Columbia Parkway
Cincinnati, Ohio 45226

Re: Docket #105, Process for Updating the List of Hazardous Drugs (Appendix A) for the *NIOSH Alert on Hazardous Drugs*

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the proposed update to the list of hazardous drugs for the *NIOSH Alert on Hazardous Drugs*. ASHP represents pharmacists who practice in hospitals and health systems. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP is pleased that the National Institute for Occupational Safety and Health (NIOSH) held a public meeting and commends the agency for encouraging public and stakeholder input in the process for defining hazardous drugs and updating the list of these drug products. During the August 28, 2007 public meeting, Cynthia Reilly, R.Ph., Director, Clinical Standards and Quality for ASHP provided oral comments. The following written comments are a follow-up to the oral comments presented at that meeting.

ASHP has long supported the safe handling of hazardous drugs that may present an acute or chronic occupational hazard to health care practitioners. ASHP considers the protection of these individuals to be of paramount importance. However, the Society would advise caution in the evaluation and classification of drug products. When a drug is defined as "hazardous" health care practitioners must follow strict standards of practice for the receipt, storage, preparation, transport, administration, and disposal of that drug product.[1] These standards, which are designed to ensure the safety of health care workers, will place undue burden on health systems in terms of time, resources, and costs if the designation of hazardous is applied to drug products for which toxicity from occupational exposure has not been demonstrated and is unlikely.

ASHP is pleased to provide NIOSH with the following comments related to the proposed update to the list of hazardous drugs. Attachment A provides recommendations for each of the proposed drugs and the American Hospital Formulary System classification, when available. The Society recommends that the highlighted drug products in this appendix undergo in-depth assessment and discussion by the expert panel as part of their process to provide recommendations to NIOSH on the appropriateness of the proposed list. ASHP welcomes the opportunity to participate in that expert panel, along with representatives from the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), industry, academia, and professional and patient advocacy groups.

Key Recommendations:

1. ASHP supports the designation as a hazardous drug for those medications on the proposed list that are traditional antineoplastic agents and other drug products that are included or are similar in classification and mechanism to drugs designated as known or probable human carcinogens by the World Health Organization's International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP). ASHP also supports this designation for drugs for which the material safety data sheet (MSDS) or manufacturer's product labeling recommends precautions for handling, administering, and disposing of the agent.

   ASHP strongly believes that improper designation of drugs as hazardous would place undue burden on health systems, health care practitioners, and other facility personnel. Hazardous classification should be supported by evidence that exposure in the workplace would present a hazard to the health care practitioner. All staff involved in receipt, storage, preparation, transport, administration, and disposal of medications designated as hazardous would be considered at risk for occupational exposure and should adhere to the recommended guidelines for handling these products. Therefore, NIOSH's recommendations will impact the following areas of practice:

- Facilities and Equipment—Proper ventilation and engineering controls are necessary in settings where hazardous products are handled, including the use of biological safety cabinets or isolators with external exhaust as well as distinct storage and preparation areas with proper airflow and exchange. Implementing these controls would present undue burden on those who own or manage the health care facility when the medication presents no, or undocumented, occupational risk. This burden would be substantial in some practice settings—including home, ambulatory, and long-term care infusion centers; private physician offices; clinics; retail pharmacies; and nursing homes—where facilities would be required to re-design, install, and maintain new equipment to meet guidelines for handling hazardous drugs.

  Increased costs are also associated with procuring, storing, and disposing of additional personal protective equipment (including gowns, gloves, eyewear, etc.) for individuals directly involved in product preparation and administration and for staff in environmental services, patient transport, and non-clinical staff who transport these drug products. Those involved in shipping and receiving drug products would be required to wear personal protective equipment at all times, unless manufacturers and distributors used segregated and easily recognizable shipping cartons for these products. The use of spill kits and respirators (which could be required in areas without proper ventilation, such as product receiving areas and patient rooms) add to operational costs.

  In addition to increasing the required pharmacy space dedicated to the storage of hazardous products, there is the potential for cross contamination when drugs that have no or minimal risk are stored in close proximity to those with higher and documented occupational exposure risk (e.g., antineoplastics). Modification of existing storage areas would also be required in satellite pharmacies, clinics, and physician offices. Several of the proposed agents (e.g., ramelteon) that are commonly provided as samples by physician offices in the community setting would also require special handling.

- Staffing and Training Requirements—Staffing needs would likely increase to ensure coverage for employees that request alternative duty. If a high volume of these drugs are used at an individual facility, it may be necessary to assign dedicated staff for receiving, dispensing, and administration of these products. The impact would be greatest for agents, such as ramelteon and risperidone, that are widely prescribed and used in a variety of patient care units, including those areas that are staffed by personnel not typically involved in handling hazardous drugs. Pharmacy would be required to handle all modifications to dosage formulations, such as crushing or breaking tablets. The need for extemporaneous compounding would also likely increase. The proposed designation would also increase both the number of staff who require training and the complexity of that training. All individuals who handle hazardous drugs must be trained according to

the organization's hazard plan (e.g., MSDS access, procedures for managing spills, labeling requirements, etc.). Therefore, in addition to nursing and pharmacy personnel, staff in patient transport, shipping and receiving, and numerous other areas would require additional training. In light of staffing shortages in professions such as nursing and pharmacy, the proposed list of hazardous drugs would place an additional burden on the health care system.

The proposed recommendations will also affect patients and family members or caregivers providing care for those receiving these medications. Educational needs and the time required for patient counseling would increase due to the need to ensure proper handling and disposal of these drugs. Although this is anticipated for medications with established risk, inclusion of medications, such as efavirenz, that pose limited risk would place additional burden on patients and caregivers and pharmacists and other health care practitioners involved in providing patient education.

- Surveillance—Medical surveillance and quality control activities (e.g., air sampling) associated with these drugs will increase the time, costs, and administrative oversight associated with the medication use process.

- Environmental—Experts in managing pharmaceutical waste do not expect the proposed drugs to be considered hazardous wastes based on current interpretation of the Environmental Protection Agency's (EPA) Resource Conservation and Recovery Act. However, because the EPA's designation of hazardous waste has not been updated since 1976, health care practitioners often refer to the NIOSH list for guidance in waste disposal. At a minimum, experts recommend incineration for drugs on the NIOSH list that are not antineoplastic agents and special waste management for antineoplastics. Outside of the pharmacy, processes for disposal of waste in nursing units, physician offices, and patient homes would need to be enhanced. Strict cleaning and decontamination procedures also would need to be followed in all preparation and clinical areas where these products are handled. The time and cost associated with these processes must also be considered.

Facilities that are unable or chose not to comply with the standards described here would not prepare or dispense these medications. Therefore, the proposed hazardous drug list may have the unintended consequence of limiting patient access to drug therapy.

2. Additional discussion is warranted for drugs for which no harm is anticipated from occupational exposure, in particular when the classification is based on *in vitro* studies or limited animal or human models where toxicity is consistent only with extended internal dosing (which reflects drug uptake, metabolism, and excretion) in the intended patient. Medications on the proposed list that fall within this category

include aripiprazole, divalproex, amiodarone, eszopiclone, and several others. These drugs have similar long-term exposure toxicology profiles to other medications (e.g., ACE inhibitors) that have not been designated as hazardous drugs. At present, there is no evidence to support the assertion that limited exposure to these agents in the workplace presents a health risk to the health care practitioner. A formal risk assessment that includes the extent of workplace and worker contamination (e.g., air and surface contamination, dermal contact and skin absorption, and urine testing) may be warranted. It would be premature to designate these drugs as hazardous before such evidence is available.

3. In addition to the inherent toxicity of the drug, the extent of occupational exposure should be considered. Exposure and risk to health care practitioners is limited with solid dosage formulations, such as capsules and coated tablets. Touch-to-mouth contamination, which presents the most likely risk for these medications, would be appropriately addressed by existing hand hygiene recommendations.[2] However, ASHP acknowledges that there is risk associated with manipulating these dosage formulations (e.g., opening capsules and crushing or breaking tablets) or other situations that cause stress on the formulation, such as repackaging operations. Additional caution is recommended in these scenarios. NIOSH may also wish to re-evaluate classification of some solid oral dosage forms (e.g., oral contraceptives) that were designated as hazardous based on the 2004 publication.

4. Characteristics of the health care practitioner are another important factor in determining toxicity. For example, immunocompromised individuals must use precautions when handling drugs such as alefacept, whereas this drug would not be expected to cause toxicity in individuals with an intact immune system. Likewise, handling of bonsentan by women of child-bearing age is hazardous because of its potential teratogenic effects, but would not be harmful to a male health care practitioner. The list of medications that may be harmful to specific populations extends beyond those found on the NIOSH list. It may be more appropriate to advise use of universal precautions to those groups rather than enforcing restrictions more broadly.

5. Some monoclonal antibody products appear to be designated as hazardous strictly based on their AHFS classification as an antineoplastic agent. However, some researchers have noted that these drug molecules are too large for absorption through intact skin.[3] In the absence of accidental injection or a skin condition that would allow absorption, the occupational exposure with normal preparation and administration of these drugs is expected to be minimal. However, ASHP recognizes that this rationale is controversial and recommends additional discussion of these agents by the expert panel.

6. As discussed at the August meeting, ASHP supports the re-evaluation of select agents designated as hazardous in the 2004 *NIOSH Alert on Hazardous Drugs.* These agents

include bacille Calmette-Guérin vaccine, oxytocin, epinephrine, and oral contraceptives. In addition, there are older medications, such as muromonab, that were not previously categorized as hazardous that should be evaluated for possible inclusion on the hazardous drug list.

7. Research and anecdotal feedback have shown that health care practitioners may not comply with recommended precautions that are perceived as overly restrictive or cumbersome.[4,5] Some drugs proposed for addition to the NIOSH hazardous drug list, such as those used to induce sleep, may have the unintended effect of further decreasing practitioners' compliance to safety precautions. Despite the classification of hazardous, it's likely that practitioners will continue to view those agents as harmless. In turn, this relaxed perception could extend to the handling of all drug products designated as hazardous, even those with known risk.

8. ASHP recognizes that there may be hazards of extended or repeated exposure to agents that present limited risk for short-term occupational exposure. In the absence of altering the proposed designation of these agents as hazardous, NIOSH may wish to consider stratification of risk based on the formulation, drug mechanism, inherent toxicity, and the anticipated extent of exposure. It also may be useful to further define what represents an occupational exposure.

9. Feedback from ASHP members indicates that some practice sites have implemented a tiered approach to handling hazardous drugs, with the intent of balancing the risks of occupational exposure and the practical aspects of the medication use process. ASHP supports use of a tiered approach, but believes that classification on the institutional level can lead to increased confusion on the part of risk management staff and the pharmacists, nurses, technicians, and others who handle these products. The former are concerned about liability (should harm occur) and the latter are confused by the mixed message of a hazardous designation by NIOSH when no precautions are required at the individual practice site.

   Therefore, ASHP supports development of a process whereby input from organizations such as NIOSH and the product manufacturers would be used to determine and assign the level of risk associated with a given drug and the recommended precautions for handling that drug. In addition, ASHP supports efforts to require this information under the Food and Drug Administration labeling requirements.

   The assignment of tier and the recommended precautions should be carefully considered, but one scenario would be a two-tier system that includes:

   a. LOW RISK—medications that pose the lowest risk to the health care practitioner, in particular those in intact forms, such as vorinostat. Chemotherapy or nitrile gloves should be used when handling these products,

but masks and gowns would be optional. When opened, split, or crushed, medications in this category would require enhanced precautions.

b. HIGH RISK—medications that pose the highest risk to the health care practitioner, such as intravenous chemotherapy and agents on the IARC and NTP known and probable carcinogen lists. Gown, glove, and mask use would be required.

ASHP favors a two-tier system, but some institutions have implemented a three-tier system that permits use of intermediate precautions for solid oral dosage forms of chemotherapy or manipulated dosage forms of low-risk drugs. ASHP recognizes that any proposed stratification would increase the need for health care practitioner education.

10. Finally, ASHP recommends, and would like to participate in, educational efforts to improve health care practitioners' knowledge and use of appropriate precautions when handling hazardous drugs. The traditional view that hazardous drug exposure is limited to oncology medications persists. There is an ongoing need to increase awareness about risks associated with other hazardous drugs and the use of antineoplastic drugs for nontraditional uses, such as rheumatoid arthritis, lupus, nephritis, and multiple sclerosis. Additional educational efforts should be directed to housekeeping, patient transport, and nonclinical staff who may be exposed to hazardous drug products or wastes. Education that instructs on the proper use, and limitations, of personal protective equipment should also be enhanced.

ASHP appreciates this opportunity to present the Society's written comments pertaining to the definition of hazardous drugs and proposed additions to the existing list of hazardous drugs in the workplace. Feel free to contact Cynthia Reilly if you have any questions regarding our comments. She can be reached by telephone at (301) 664-8664, or via e-mail at creilly@ashp.org.

Sincerely,

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs

References

1. American Society of Health-System Pharmacy. ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006: 63:1172-93.

2. World Health Organization. WHO Guidelines on Hand Hygiene in Health Care: A Summary. France: WHO, 2005. http://www.who.int/patientsafety/events/05/HH_en.pdf (Accessed 2007 Aug 27).

3. Bos JD and Meinardi MMHM. The 500 Dalton rule for the skin penetration of chemical compounds and drugs. *Exp. Dermatol.* 2000;9;165-9.

4. Mahon SM, Casperson DS, Yackzan S, et al (1994). Safe handling practices of cytotoxic drugs: The results of a chapter survey. *Oncology Nursing Forum.* 1994;*21*, 1157-65.

4. Nieweg RM, deBoer M, Dubbleman RC, et al. (1994). Safe handling of antineoplastic drugs. Results of a survey. *Cancer Nursing*, *17*(6), 501-511.

Attachment A

DRAFT ASHP Recommendations for the Proposed Update to the *NIOSH Alert on Hazardous Drugs*

ASHP recommends that drugs indicated with an asterisk in capitalized text not be designated as hazardous. Highlighted drug products are recommended for additional assessment and discussion prior to classification as a hazardous drug.

GENERIC NAME	AHFS CLASSIFICATION	RATIONALE FOR RECOMMENDED CLASSIFICATION
*** ARIPIPRAZOLE**	**ANTIPSYCHOTIC AGENTS (28:16.08)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM ORAL COATED FORMULATION**
Pemetrexed Disodium	ANTINEOPLASTIC AGENTS (10:00)	Appropriate per mechanism and formulation
Alefacept	SKIN AND MUCOUS MEMBRANE AGENTS, MISC. (84:92)	Inherent toxicity from occupational exposure may be limited; large molecular size
*** LUBIPROSTONE**	**GI DRUGS, MISCELLANEOUS (56:92)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
*** APOMORPHINE HYDROCHLORIDE**	**CENTRAL NERVOUS SYSTEM AGENTS, MISC. (28:92)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE**
Nelarabine	ANTINEOPLASTIC AGENTS (10:00)	Appropriate per mechanism and formulation
Bevacizumab	ANTINEOPLASTIC AGENTS (10:00)	Exposure risk may be limited based on molecular size

GENERIC NAME	AHFS CLASSIFICATION	RATIONALE FOR RECOMMENDED CLASSIFICATION
* RASAGILINE MESYLATE	CENTRAL NERVOUS SYSTEM AGENTS, MISC. (28:92)	LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION
* ENTECAVIR	NUCLEOSIDES AND NUCLEOTIDES (8:18.32)	LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE
* VARENICLINE TARTRATE	AUTONOMIC DRUGS, MISCELLANEOUS (12:92)	LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION
Clofarabine	ANTINEOPLASTIC AGENTS (10:00)	Appropriate per mechanism
* AMIODARONE HYDROCHLORIDE	ANTIARRHYTHMIC AGENTS (24:04.04)	LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION
Decitabine	ANTINEOPLASTIC AGENTS (10:00)	Appropriate per mechanism
* VALPROATE SODIUM, VALPROIC ACID, DIVALPROEX SODIUM	ANTICONVULSANTS, MISCELLANEOUS (28:12.92)	LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; HOWEVER INCREASED EXPOSURE RISK FROM ORAL LIQUID FORMULATIONS
Medroxyprogesterone Acetate	PROGESTINS (68:32)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited occupational exposure risk

GENERIC NAME	AHFS CLASSIFICATION	RATIONALE FOR RECOMMENDED CLASSIFICATION
Pimecrolimus	SKIN AND MUCOUS MEMBRANE AGENTS, MISC. (84:92)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; although formulation may present increased risk, exposure is limited by packaging and carcinogenicity is consistent only with long term use
Cetuximab	ANTINEOPLASTIC AGENTS (10:00)	Exposure risk may be limited based on molecular size
*** ZIPRASIDONE**	**ANTIPSYCHOTIC AGENTS (28:16.08)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
Imatinib Mesylate	ANTINEOPLASTIC AGENTS (10:00)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited exposure risk from formulation
*** ZALCITABINE**	**NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS (8:18.08.20)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM ORAL FORMULATIONS**
Topotecan Hydrochloride	ANTINEOPLASTIC AGENTS (10:00)	Appropriate per mechanism
Mecasermin	SOMATOTROPIN AGONISTS (68:30.04)	Exposure risk may be limited based on molecular size
Palifermin	CELL STIMULANTS AND PROLIFERANTS (84:16)	Exposure risk may be limited based on molecular size

GENERIC NAME	AHFS CLASSIFICATION	RATIONALE FOR RECOMMENDED CLASSIFICATION
Cladribine	ANTINEOPLASTIC AGENTS (10:00)	Appropriate per mechanism
* ESZOPICLONE	**ANXIOLYTICS, SEDATIVES & HYPNOTICS,MISC. (28:24.92)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
* PREGABALIN	**ANTICONVULSANTS, MISCELLANEOUS (28:12.92)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
Strontium-89 Chloride	RADIOACTIVE AGENTS (78:00)	Appropriate per mechanism, but existing precautions for nuclear pharmacy may provide sufficient health care worker protection
* MICAFUNGIN SODIUM	**ECHINOCANDINS (8:14.16)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE**
Alglucosidase Alfa	ENZYMES (44:00)	Limited or no evidence of toxicity based on published studies and prescribing information
Sorafenib Tosylate	ANTINEOPLASTIC AGENTS (10:00)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited exposure risk from formulation
Abatacept	MISCELLANEOUS THERAPEUTIC AGENTS (92:00)	Exposure risk may be limited based on molecular size

GENERIC NAME	AHFS CLASSIFICATION	RATIONALE FOR RECOMMENDED CLASSIFICATION
*** PAROXETINE HYDROCHLORIDE**	**ANTIDEPRESSANTS (28:16.04)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
Pentetate calcium trisodium	MISCELLANEOUS THERAPEUTIC AGENTS (92:00)	Appropriate per mechanism
Porfimer Sodium		May be appropriate based on mechanism and route of administration
Medroxyprogesterone	PROGESTINS (68:32)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited risk of exposure with oral formulation
Samarium 153	RADIOACTIVE AGENTS (78:00)	Appropriate per mechanism, but existing precautions for nuclear pharmacy may provide sufficient health care worker protection
Sirolimus	MISCELLANEOUS THERAPEUTIC AGENTS (92:00)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited risk of exposure with oral formulation
Lenalidomide	MISCELLANEOUS THERAPEUTIC AGENTS (92:00)	Consistent with previous classification of similar agents and pregnancy category, but limited risk outside of pregnancy
*** RISPERIDONE**	**ANTIPSYCHOTIC AGENTS (28:16.08)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE**

GENERIC NAME	AHFS CLASSIFICATION	RATIONALE FOR RECOMMENDED CLASSIFICATION
Rituximab	ANTINEOPLASTIC AGENTS (10:00)	Exposure risk may be limited based on molecular size
*** RAMELTEON**	**ANXIOLYTICS, SEDATIVES & HYPNOTICS,MISC. (28:24.92)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
*** QUETIAPINE FUMARATE**	**ANTIPSYCHOTIC AGENTS (28:16.08)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
Tiotropium Bromide Monohydrate	ANTIMUSCARINICS/ ANTISPASMODICS (12:08.08)	Potential irritant, but similar products are not classified as hazardous
Dasatinib	ANTINEOPLASTIC AGENTS (10:00)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited exposure risk from formulation
*** EFAVIRENZ**	**ANTIRETROVIRALS (8:18.08)**	**CONSISTENT WITH PREVIOUS CLASSIFICATION OF SIMILAR DRUGS, BUT ADDITIONAL EVALUATION IS WARRANTED; LIMITED RISK OF EXPOSURE WITH ORAL FORMULATION**
Sunitinib Malate	ANTINEOPLASTIC AGENTS (10:00)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited exposure risk from formulation

GENERIC NAME	AHFS CLASSIFICATION	RATIONALE FOR RECOMMENDED CLASSIFICATION
Erlotinib Hydrochloride	ANTINEOPLASTIC AGENTS (10:00)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited exposure risk from formulation
*** TINIDAZOLE**	ANTIPROTAZOALS, MISCELLANEOUS (8:30.92)	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
Bosentan	VASODILATING AGENTS, MISCELLANEOUS (24:12.92)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited exposure risk from formulation and limited risk outside of pregnancy
*** OXCARBAZEPINE**	**ANTICONVULSANTS, MISCELLANEOUS (28:12.92)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE**
*** TIGECYCLINE**	**TETRACYCLINES (8:12.24)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE**
Natalizumab	MISCELLANEOUS THERAPEUTIC AGENTS (92:00)	Exposure risk may be limited based on molecular size
Bortezomib	ANTINEOPLASTIC AGENTS (10:00)	Consistent with previous classification of similar drugs, but additional evaluation is warranted
Azacitidine	ANTINEOPLASTIC AGENTS (10:00)	Appropriate per mechanism
*** NEVIRAPINE**	**ANTIRETROVIRALS (8:18.08)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE**

GENERIC NAME	AHFS CLASSIFICATION	RATIONALE FOR RECOMMENDED CLASSIFICATION
*** TENOFOVIR DISOPROXIL FUMARATE**	**ANTIRETROVIRALS (8:18.08)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**
Trypan Blue	MISCELLANEOUS THERAPEUTIC AGENTS (92:00)	No recommendation for this agent at this time.
Vorinostat	ANTINEOPLASTIC AGENTS (10:00)	Consistent with previous classification of similar drugs, but additional evaluation is warranted; limited risk of exposure with oral formulation
*** ZONISAMIDE**	**ANTICONVULSANTS, MISCELLANEOUS (28:12.92)**	**LIMITED INHERENT TOXICITY FROM OCCUPATIONAL EXPOSURE; LIMITED EXPOSURE RISK FROM FORMULATION**